

Effect of Changes in Human Exposure Regulations on Quality Assurance

A New Paradigm of Field QA

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What Does This Mean?

Learn to QA that
which cannot be
QA'd

Blast From the Past

- QAE Officers?
- Quality Assurance & Ethics
 - Check Worker Consent
 - No coercion
 - Can opt out at any time
 - Meet minimum requirements
 - Experience
 - Age
 - Monitor Working Conditions
 - Heat Stress/Dehydration

New Rule

- 40 CFR, Part 26: Protection of Human Subjects
 - Subpart A: Basic EPA Policy for Protection
 - Subpart B: Prohibition of Research
 - Subpart C: Observational Research - Women
 - Subpart D: Observational Research – Children
 - Subpart K: Basic Ethical Requirements
 - Subpart L: Prohibition of Third-Party Research
 - Subpart M: Requirements for Submission
 - Subpart O: Actions for Noncompliance
 - Subpart P: Review of Research
 - Subpart Q: Ethical Standards

People to Know

- Human Studies Review Board (HSRB)
 - Advisory panel to EPA
 - Appointed by Congress
 - Must review all proposed research involving human subjects (except “observational” studies)
- Institutional Review Board (IRB)
 - Private Companies
 - Membership made up of cross-section
 - Must review all proposed research
 - Protocols
 - Informed consent forms
 - Any information given to workers

Timeline

- Sponsor Develops Study Plan
- Protocol Prepared
- All documents undergo IRB review
- All documents submitted to EPA/HSRB
- With approval, study may begin....
- Otherwise, revisions will be necessary and whole process starts over.
- This adds at least 6 months lead time to starting a field study

QA Concerns

Pre-study Issues (Subpart K):

- §26.1115(a)(1): All materials submitted to an IRB
- §26.1115(a)(2): Minutes of IRB meeting(s) documented
- §26.1115(a)(4): Copies of IRB correspondence maintained
- §26.1115(a)(6): SOPs submitted to IRB

QA Concerns

Protocol Issues (Subpart K):

- §26.1125(a)(1): Potential risks discussed
- §26.1125(a)(2): Measure taken to reduce risk
- §26.1125(a)(3): Nature of benefits discussed
- §26.1125(a)(4): Alternative means of obtaining data
- §26.1125(a)(5): Balance of Risk vs. Benefits

QA Concerns

Protocol Issues (Subpart K):

- §26.1125(b): All info/documents reviewed by an IRB
- §26.1125(c): Recruitment procedures
- §26.1125(d): Description of Methods of Presenting Information (consent process)
- §26.1125(e): Documentation of correspondence
- §26.1125(f): Official notification from an IRB has been received

QA Concerns

Field Research (Subparts B, K, & M):

– §26.203: Prohibitive Research

- Assure that female participants are not pregnant
- Assure that no participants are under 18 years old

– §26.1117: Documentation of Informed Consent

- Can't be present during consent
- Can only review signed confidential consent forms

– §26.1303: Submission of Information

- Assure that all appropriate ethical documentation is complete

What This Really Means

- More Paperwork
 - Protocol size has almost tripled (15 pgs – 40+ pgs)
 - Final Reports will also have increased sections
 - New SOPs are needed to meet HSRB requirements
 - Recruitment of Participants
 - Consenting Processes
 - Language Requirements
 - Mitigation of Risks
 - Handling Confidential Personal Information
 - Flexibility for QAUs to be able to assure compliance without being able to audit everything

AHETF SOPs

- Personnel Responsibilities – Ethics Training
- Procedure for Recruiting Study Participants
- Archiving Confidential Worker Information
- Ethical Requirements for Studies
- Recruiting Volunteers
- Worker Health Status
- Pregnancy Testing
- Pesticide Safety Precautions
- Adverse Events Reporting for IRB

AHETF SOPs

- Identification and Control of Heat Stress
- Emergency Procedures for Human Subjects
- Language Considerations
- Informed Consent of Study Volunteers
- Compiling Lists of Potential Growers
- Compiling Lists of Potential Applicators
- Recruiting Eligible Growers/Applicators
- ???

15 New SOPs with 14 revisions in past 12 months

Developing the Process

- Only Audited Three Studies
 - One was an “Observational” Study
 - Not scripted, but purely watching workers do a normal daily routine
 - Samples still collected as usual
 - Two were typical field Worker Exposure Studies
 - Applicator Only
 - One worker per day
 - Some workers were randomly selected at time of study
- Plans for Conducting Future Audits
 - Still Developing this Process
 - Policy in place to review all consent forms immediately after consenting process completed
 - QAU to have taken certified ethics course, as all study team members are required

In Conclusion

- Standard GLP Audits Still Conducted
 - Documentation
 - SOPs
 - Protocols
- Adapt new Ethical Regulations to QA Policy
 - Be able to assure that the intangibles are met
 - Assure researchers are following ethical rules
 - Verify what little documentation is associated
- It's a learning process that will take some time to get completely assimilated. Just like the GLPs 20 years ago!